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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/486,142 03/31/00 MARTINEZ

J 427.034

EXAMINER

HM22/0515

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TAYLOR, J	
ART UNIT	PAPER NUMBER

1655

10

DATE MAILED:

05/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/486,142

Applicant(s)

MARTINEZ ET AL.

Examiner

Janell Taylor Cleveland

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-25 is/are rejected.
- 7) ☒ Claim(s) 11-13 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. This is a CPA of applicant's earlier Application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 and 14-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the phrase "...Y3 and Y4 independently represent a trinucleotide which codes for Arg or Lys..." However, it is not

Art Unit: 1655

clear if they both code for Arg or Lys. In other words, is it possible to have Arg-Arg or Lys-Lys, etc., or is it possible that together they code for a single amino acid, Arg or Lys. This could be corrected by amending the claim to read "Y3 codes for a trinucleotide representing Arg or Lys, Y4 codes for a trinucleotide coding for Arg or Lys..."

Appropriate correction is required.

4. Claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the term "DNA bank", however, it is not clear what is meant by this phrase and no clear definition is recited in the specification. This could be clarified by amending the claims to read "DNA sample" which is well known and accepted terminology in the art.

5. Claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the phrase "method for identification of the precursor..." It is not clear what is meant by the word "precursor" in this context. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-10, 16-17, and 20-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Onda et al. (USPN 5,756,295).

The claims are drawn to a single stranded oligonucleotide OX characterized in that it comprises 9 to 42 nucleotides and is capable of hybridizing under mild or stringent conditions with an oligonucleotide OY of the sequence Y1-Y2-Y3-Y4-Y5, in which Y1 represents a nucleotide sequence of 1 to 12 nucleotides of Y1 is suppressed, Y2 represents a trinucleotide which codes for Arg or Lys, and Y5 represents a nucleotide sequence of 1 to 21 nucleotides in length or is suppressed. Further embodiments include Y5 representing a nucleotide sequence Y6-Y7-Y8-Y9, in which Y6 represents a trinucleotide which codes for Ser, Thr, Tyr, Y7 represents a trinucleotide which codes for any amino acid, Y8 represents a trinucleotide which codes for Glu or Asp and Y9 represents a nucleotide sequence comprising 1 to 12 nucleotides. Other claims, such as 16-17 and 20-25, are drawn to a method for identification of the precursor of a peptide having an amidated C-terminal end, characterized in the following successive stages: obtaining a DNA bank; hybridization of one or more oligonucleotides according to any one of claims 1-7 with the said DNA bank; identification of the DNA sequence or sequences of the said bank which hybridizes with an oligonucleotide according to claim 1, identification in this sequence of one or more precursors of peptides with a possible amidated C-terminal end.

Onda et al. teach DNA primers each having a nucleotide sequence substantially complementary to a nucleotide sequence which codes for Gly-Lys-Arg, Gly-Lys-Lys, or Gly-Arg-Arg (Abstract). Onda et al. also teaches that probes or primers of this

Art Unit: 1655

sequence may be labeled. Onda teaches that "...there are many cases that useful physiologically active substances or precursor thereof lie between two basic amino acid residues (e.g., Lys-Lys, Lys-Arg, etc.) at the N-terminal side and three amino acid residues (e.g. Gly-Lys-Lys, etc) at the C-terminal side. In an embodiment, human endothelial-3 has an amino acid sequence comprising 21 amino acid residues which extend from the 97th to the 117th amino acid residues in the amino acid sequence..." (Col. 3, bridging Col. 14). Onda et al. also teaches the use of a DNA library, and states that "...it has been carried out already to screen the DNA fragments from a DNA library by means by means of PCR..." (Col. 2, lines 45-50).

Since the claims are drawn to the oligonucleotide OX, which hybridizes to OY, even though the exact sequence of OY is not taught, the claims are not drawn to that sequence. Onda does teach a primer or probe which fits the description of OX: it is 9 sequences in length, it hybridizes to an oligonucleotide which contains the nucleotides which represents the amino acids Gly-Lys-Lys, Gly-Lys-Arg, etc.

Summary

Claims 1-7 and 14-25 are rejected under 35 U.S.C. 112, second paragraph. Claims 1-10, 16-17, and 20-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Onda et al. Claims 11-15 and 18-19 are free of the prior art because they teach unique sequences, OZ and OY, but are objected to for depending from a rejected claim. Claims 14, 15, and 18-19 are free of the prior art but are rejected for other reasons.

Art Unit: 1655

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

May 7, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

5/14/01